



Final Regulation Agency Background Document

Agency name	Board of Medicine, Department of Health Professions
Virginia Administrative Code (VAC) citation	18VAC85-130-10 et seq.
Regulation title	Regulations Governing the Practice of Licensed Midwives
Action title	Disclosures of risks to certain clients
Date this document prepared	10/21/11

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 14 (2010) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual*.

Brief summary

Please provide a brief summary (no more than 2 short paragraphs) of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed. Alert the reader to all substantive matters or changes. If applicable, generally describe the existing regulation. Also, please include a brief description of changes to the regulation from publication of the proposed regulation to the final regulation.

The Board of Medicine, with unanimous approval from the Advisory Board on Midwifery, approved proposed regulations to require midwives to disclose to their clients, when certain antepartum or intrapartum conditions exist, options for consultation and referral to a physician and evidence-based information on health risks associated with a home birth.

Statement of final agency action

Please provide a statement of the final action taken by the agency including (1) the date the action was taken, (2) the name of the agency or board taking the action, and (3) the title of the regulation.

On October 20, 2011, the Board of Medicine adopted final amendments to 18VAC85-130-10 et seq., Regulations Governing the Practice of Licensed Midwives.

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including (1) the most relevant law and/or regulation, including Code of Virginia citation and General Assembly chapter number(s), if applicable, and (2) promulgating entity, i.e., agency, board, or person. Describe the legal authority and the extent to which the authority is mandatory or discretionary.

Regulations are promulgated under the general authority of Chapter 24 of Title 54.1 of the Code of Virginia. Section 54.1-2400, which provides the Board of Medicine the authority to promulgate regulations to administer the regulatory system:

§ 54.1-2400 -General powers and duties of health regulatory boards

The general powers and duties of health regulatory boards shall be:

- 1. To establish the qualifications for registration, certification or licensure in accordance with the applicable law which are necessary to ensure competence and integrity to engage in the regulated professions.*

- 2. To examine or cause to be examined applicants for certification or licensure. Unless otherwise required by law, examinations shall be administered in writing or shall be a demonstration of manual skills.*

- 3. To register, certify or license qualified applicants as practitioners of the particular profession or professions regulated by such board.*

- ...*
- 6. To promulgate regulations in accordance with the Administrative Process Act (§ 9-6.14:1 et seq.) which are reasonable and necessary to administer effectively the regulatory system. Such regulations shall not conflict with the purposes and intent of this chapter or of Chapter 1 (§ [54.1-100](#) et seq.) and Chapter 25 (§ [54.1-2500](#) et seq.) of this title. ...*

A specific regulatory mandate for the Board of Medicine is found in § 54.1.2957.9:

§ [54.1-2957.9](#). Regulation of the practice of midwifery.

*The Board shall adopt regulations governing the practice of midwifery, upon consultation with the Advisory Board on Midwifery. The regulations shall (i) address the requirements for licensure to practice midwifery, including the establishment of standards of care, (ii) be consistent with the North American Registry of Midwives' current job description for the profession and the National Association of Certified Professional Midwives' standards of practice, except that prescriptive authority and the possession and administration of controlled substances shall be prohibited, (iii) ensure independent practice, (iv) **require midwives to disclose to their patients, when appropriate, options for consultation and referral to a physician and evidence-based information on health risks associated with birth of a child***

outside of a hospital or birthing center, as defined in subsection E of § [32.1-11.5](#), including but not limited to risks associated with vaginal births after a prior cesarean section, breech births, births by women experiencing high-risk pregnancies, and births involving multiple gestation, (v) provide for an appropriate license fee, and (v) (vi) include requirements for licensure renewal and continuing education. Such regulations shall not (a) require any agreement, written or otherwise, with another health care professional or (b) require the assessment of a woman who is seeking midwifery services by another health care professional.

License renewal shall be contingent upon maintaining a Certified Professional Midwife certification.

Purpose

Please explain the need for the new or amended regulation. Describe the rationale or justification of the proposed regulatory action. Detail the specific reasons it is essential to protect the health, safety or welfare of citizens. Discuss the goals of the proposal and the problems the proposal is intended to solve.

The purpose of the regulatory action is compliance with a legislative mandate for the adoption of regulations relating to disclosures of risk to certain patients. The law was amended by HB2163 (Chapter 646 of the 2009 Acts of the Assembly) to require the Board to adopt regulations governing the practice of midwifery, upon consultation with the Advisory Board on Midwifery. The regulations shall require midwives to “disclose to their patients, when appropriate, options for consultation and referral to a physician and evidence-based information on health risks associated with birth of a child outside of a hospital or birthing center, as defined in subsection E of § [32.1-11.5](#), including but not limited to risks associated with vaginal births after a prior cesarean section, breech births, births by women experiencing high-risk pregnancies, and births involving multiple gestation.”

The amendments set out the conditions or risks factors for which it is “appropriate” to disclose the options available for referral and consultation and to provide the evidence-based information to a client about risks associated with birth outside of a hospital or birthing center for women with certain conditions or clinical situations.

In Virginia, the Code requires that regulations to be consistent with the North American Registry of Midwives' (NARM) current job description for the profession. The NARM Position Paper on the Practice of Midwifery states that: “Certified Professional Midwives (CPMs) ...have demonstrated the knowledge and skills to provide full prenatal, birth, and postpartum care to low-risk women, to recognize deviations from normal, and to refer, consult, or transfer care if appropriate.” The proposed regulation is consistent with the NARM model in which midwives are expected to appropriately assess deviations from the normal and to disclose to clients those conditions or situations in which an out-of-hospital birth is not appropriate or those that may present certain risks to a woman or her baby.

The goal for the amended regulation is to ensure that women are adequately informed of any risk for home birth associated with certain health conditions or prior birth history. Regulation of risk

disclosure requires that women are adequately assessed and informed of the condition which presents increased risk for home birth and ensure that the choice of provider and birth setting are made with full disclosure of risk.

Substance

Please identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. A more detailed discussion is required under the "All changes made in this regulatory action" section.

The amended regulations include the following:

- 1) A requirement that, upon initiation of care, the midwife review the woman's medical history, including records from prior pregnancies in order to identify pre-existing conditions that require disclosure of risk for home birth. The midwife will also be required to continually assess the pregnant woman in order to recognize conditions that may arise during the course of care that require disclosure of risk for home birth.
- 2) A listing of those factors or criteria that require disclosure that the client is not an appropriate candidate for an out-of-hospital birth, and a listing of those factors or criteria that require disclosure relating options for consultation and referral.
- 3) If the factors or criteria have been identified that may indicate health risks associated with birth of a child outside a hospital, a requirement for the midwife to provide evidence-based information on such risks. Such information would be specified by the Board for certain conditions and would include statements and evidence from both the medical and midwifery models of care.

A requirement for documentation in the client record of the assessment, the presence or absence of high risks, and, if appropriate the provision of disclosures and evidence-based information.

Issues

Please identify the issues associated with the proposed regulatory action, including:

- 1) *the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions;*
 - 2) *the primary advantages and disadvantages to the agency or the Commonwealth; and*
 - 3) *other pertinent matters of interest to the regulated community, government officials, and the public.*
- If there are no disadvantages to the public or the Commonwealth, please indicate.*

- 1) The primary advantage to the public (clients of midwifery) is the assurance that an appropriate assessment of health risks has been made and documented, that disclosure of such risks has been given to the client, and that evidence-based information on risks has been made available. The advantage to licensed midwives is the existence of a clear regulatory standard by which to practice. There are no disadvantages, because consumer choice will not be abridged.

- 2) There are no advantages or disadvantages to the agency or the Commonwealth.
- 3) There are no other pertinent matters of interest.

Changes made since the proposed stage

Please describe all changes made to the text of the proposed regulation since the publication of the proposed stage. For the Registrar’s office, please put an asterisk next to any substantive changes.

There are no changes in the text.

Public comment

Please summarize all comments received during the public comment period following the publication of the proposed stage, and provide the agency response. If no comment was received, please so indicate.

Commenter	Comment	Agency response
Tami Conklin	Supports the regulation; informed consent and disclosure is standard practice for midwives. Should be required for obstetricians as well.	The Board appreciates the support for proposed regulations. The mandate did not include other practitioners.
Leslie Lytle	Supports the regulation; informed consent and disclosure is standard practice for midwives. Should be required for obstetricians as well.	The Board appreciates the support for proposed regulations. The mandate did not include other practitioners.
Katherine Hoffman	Supports the regulation; informed consent and provision of evidence based information is standard practice for midwives. Decision of the woman must be respected.	The Board appreciates the support for proposed regulations.
Frederick Friis	Supports the regulation.	The Board appreciates the support for proposed regulations.
Dr. Lori Flanagan	Supports the regulation; informed consent and disclosure is standard practice for midwives. Should be required for physicians as well.	The Board appreciates the support for proposed regulations. The mandate did not include other practitioners.
Esperanza Gracia	Supports the regulation; informed consent and disclosure is standard practice for midwives. Should be required for physicians as well.	The Board appreciates the support for proposed regulations. The mandate did not include other practitioners.
Brad Ashley	Supports the regulation.	The Board appreciates the support for proposed regulations.
Roland Winston	Supports the regulation.	The Board appreciates the support for proposed regulations.

All changes made in this regulatory action

Please list all changes that are being proposed and the consequences of the proposed changes. Describe new provisions and/or all changes to existing sections.

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change, rationale, and consequences
85	n/a	Section sets out disclosure requirements	Changes the name of the section so it references the <u>general</u> disclosure requirements and new section 86 sets out the disclosure requirements for certain high risk conditions.
n/a	86	Sections sets out disclosure requirements for certain health conditions	<p>Subsection A:</p> <ul style="list-style-type: none"> • Requires the midwife, upon initiation of care, to review the client's medical history in order to identify pre-existing conditions or indicators that require disclosure of risk for home birth. • Requires the midwife to offer standard tests and screenings for evaluating risks and to document client response to such recommendations. • Requires the midwife to continually assess the pregnant woman and baby in order to recognize conditions that may arise during the course of care that require disclosure of risk for birth outside of a hospital or birthing center. <p><i>Subsection A is intended to establish the framework for care that is reasonable and necessary in order to identify whether conditions or health risks are present that would trigger disclosures as required by law. There is not requirement that the midwife refer a client to another health care professional but there is a requirement for recommendation of tests and screenings necessary to evaluate risks.</i></p> <p>Subsection B:</p> <ul style="list-style-type: none"> • Requires the midwife to request and review the client’s medical history, including records of the current or previous pregnancies, disclose to the client the risks associated with a birth outside of a hospital or birthing center and provide options for consultation and referral – if the evaluation and review of medical history indicates that any of the conditions listed are present. • Requires the midwife to consult with or request documentation from the physician as part of the risk assessment for birth outside of a hospital or birthing center if the client is under the care of a physician for any of the listed medical conditions or risk factors. <p>Subdivision 1 lists the antepartum risks that would trigger the need for disclosure about possible risk of a home birth and the options for referral and consultation:</p> <ul style="list-style-type: none"> · Conditions requiring on-going medical supervision or on-going use of medications;

		<ul style="list-style-type: none"> · Active cancer; · Cardiac disease; · Severe renal disease -- active or chronic; · Severe liver disease -- active or chronic; · HIV positive status with AIDS; · Uncontrolled hyperthyroidism; · Chronic obstructive pulmonary disease; · Seizure disorder requiring prescriptive medication; · Psychiatric disorders; · Current substance abuse known to cause adverse effects; · Essential chronic hypertension over 140/90; · Significant glucose intolerance; · Genital herpes; · Inappropriate fetal size for gestation; · Significant 2nd or 3rd trimester bleeding; · Incomplete spontaneous abortion; · Abnormal fetal cardiac rate or rhythm; · Uterine anomaly; · Platelet count less than 120,000; · Previous uterine incision and/or myomectomy with review of surgical records and/or subsequent birth history; · Isoimmunization to blood factors; · Body Mass Index (BMI) equal to or greater than 30; · History of hemoglobinopathies; · Acute or chronic thrombophlebitis; · Anemia (hematocrit less than 30 or hemoglobin less than 10 at term; · Blood coagulation defect; · Pre-eclampsia/eclampsia; · Uterine ablation; · Placental abruption; · Placenta previa at onset of labor; · Persistent severe abnormal quantity of amniotic fluid; · Suspected chorioamnionitis; · Ectopic pregnancy; · Pregnancy lasting longer than 42 completed weeks with an abnormal non-stress test; · Any pregnancy with abnormal fetal surveillance tests; · Rupture of membranes 24 hours before the onset of labor; · Position presentation other than vertex at term or while in labor; · Multiple gestation. <p>Subdivision 2 lists the intrapartum risks that would trigger the need for disclosure about possible risk of a home birth and the options for referral and consultation:</p> <ul style="list-style-type: none"> · Current substance abuse; · Documented Intrauterine growth retardation (IUGR)/small for gestational age (SGA) at term; · Suspected uterine rupture; · Active herpes lesion in an unprotectable area; · Prolapsed cord or cord presentation; · Suspected complete or partial placental abruption; · Suspected placental previa; · Suspected chorioamnionitis; · Pre-eclampsia/eclampsia;
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		<ul style="list-style-type: none"> · Thick meconium stained amniotic fluid without reassuring fetal heart tones and birth is not imminent; · Position presentation other than vertex at term or while in labor; · Abnormal auscultated fetal heart rate pattern unresponsive to treatment or inability to auscultate fetal heart tones; · Excessive vomiting, dehydration, or exhaustion unresponsive to treatment; · Blood pressure greater than 140/90 which persists or rises and birth is not imminent; · Maternal fever equal to or greater than 100.4°; · Labor or premature rupture of membrane (PROM) less than 37 weeks according to due date. <p>Subdivision 3 specifies that if a risk factor first develops when birth is imminent, the individual midwife must use judgment taking into account the health and condition of the mother and baby in determining whether to proceed with a home birth or arrange transportation to a hospital.</p> <p><i>The listing of antepartum and intrapartum conditions or events that would necessitate a disclosure about risks of home births and the options for referral and consultation was originally taken from the midwifery rules in Oregon, but was revised and adapted for Virginia in the rulemaking process that included midwifery and obstetrics. It was agreed that the specific conditions should be listed so there was no ambiguity for midwives about their obligation to recognize and understand risk factors and to present options to their clients.</i></p> <p><i>If a client is under a physician’s care for a risk factor such as hypertension or other medical conditions, the reasonable obligation of the midwife is to consult with or request documentation from the physician as part of the risk assessment for birth outside of a hospital.</i></p> <p><i>While the presence of any of the listed conditions should indicate disclosure about risks and options for referral, the midwife is required to use her professional judgment about the risk of a home birth and the need for a transport to a hospital if the birth is imminent.</i></p> <p>Subsection C requires that if the risks factors or criteria have been identified that may indicate health risks associated with birth of a child outside a hospital or birthing center, the midwife shall provide evidence-based information on such risks. Such information shall be specified by the board in guidance documents and shall include evidence-based research and clinical expertise from both the medical and midwifery models of care.</p> <p><i>The statute requires the midwife to provide “evidence-based information on health risks associated with birth of a child</i></p>
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			<p><i>outside of a hospital or birthing center.” Subsection C is intended to implement the statute by specifying that the information will be determined in the form of guidance documents that may be adopted by the Board of Medicine and may be revised as new evidence and research becomes available. The regulations specify that the evidence-based information must represent both the medical and midwifery models of care.</i></p> <p>D. The midwife shall document in the client record the assessment of all health risks that pose a potential for a high risk pregnancy and, if appropriate, the provision of disclosures and evidence-based information. <i>Throughout the course of care, it is important for the midwife to document in a client record the conditions, recommendations and response. By specifying documentation of the potential for a high risk pregnancy and the provision of disclosures and information, regulations provide a specific standard by which the midwife can adhere to requirements set out in section 86.</i></p>
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Regulatory flexibility analysis

Please describe the agency’s analysis of alternative regulatory methods, consistent with health, safety, environmental, and economic welfare, that will accomplish the objectives of applicable law while minimizing the adverse impact on small business. Alternative regulatory methods include, at a minimum: 1) the establishment of less stringent compliance or reporting requirements; 2) the establishment of less stringent schedules or deadlines for compliance or reporting requirements; 3) the consolidation or simplification of compliance or reporting requirements; 4) the establishment of performance standards for small businesses to replace design or operational standards required in the proposed regulation; and 5) the exemption of small businesses from all or any part of the requirements contained in the proposed regulation.

Mandated by the statute, the Board has no alternative regulatory methods. **“The Board shall adopt regulations governing the practice of midwifery, upon consultation with the Advisory Board on Midwifery. The regulations shall... (iv) require midwives to disclose to their patients, when appropriate, options for consultation and referral to a physician and evidence-based information on health risks associated with birth of a child outside of a hospital or birthing center, as defined in subsection E of § 32.1-11.5, including but not limited to risks associated with vaginal births after a prior cesarean section, breech births, births by women experiencing high-risk pregnancies, and births involving multiple gestation.”**

Family impact

Please assess the impact of the proposed regulatory action on the institution of the family and family stability including to what extent the regulatory action will: 1) strengthen or erode the authority and rights of parents in the education, nurturing, and supervision of their children; 2) encourage or discourage economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one’s spouse, and

one's children and/or elderly parents; 3) strengthen or erode the marital commitment; and 4) increase or decrease disposable family income.

The proposed regulatory action has no impact on the institution of the family and family stability.